

### **REMARKS**

Claims 1, 2, 5, 6, 8-19, 24-33 and 87-113 are presently pending in the application and stand variously rejected under 35 U.S.C. §§ 112, first and second paragraphs and under the judicially-created doctrine of obviousness-type double patenting.

Claims 1, 2, 5, 11, 13, 24, 26, 28-32, 87, and 90-92 have been amended as shown above to make explicit that the zinc finger proteins are administered as nucleic acid molecules, as described throughout the specification as filed, and for clarity. Claims 20 to 23 have been canceled herein, without prejudice or disclaimer. No new matter has been entered as a result of these amendments and reconsideration of the claims is requested.

### **Specification**

The relevant paragraphs on pages 54-57 of the specification have been amended as shown above to identify sequence listing numbers. (Office Action, paragraph 2). Accordingly, the specification fully complies with the requirements of 37 C.F.R. §§ 1.821-1.825 and withdrawal of this objection is respectfully requested.

### **Inventorship**

For the Examiner's convenience, Applicants attach hereto a copy of the Petition to Change Inventorship Pursuant to 37 C.F.R. § 1.48(a) and supporting documents filed September 27, 2001. As these documents show, Fyodor Urnov was previously added as an inventor of the pending claims.

### **Rejections Under 35 U.S.C. § 112, First Paragraph, Enablement**

Claims 1, 2, 5, 6, 8-20, 24-28, 30 and 87-113 were rejected as allegedly not enabled by the specification as filed. (Office Action, paragraph 5).

Without acknowledging the correctness of this rejection<sup>1</sup>, but solely to advance prosecution of the instant application, the claims have been amended to recite provision of polynucleotides encoding zinc finger proteins. As acknowledged by the Office, the specification fully enables methods of delivery of zinc finger proteins by introduction of an expression vector. Therefore, the claims as pending are fully enabled and withdrawal of this rejection is respectfully requested.

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<sup>1</sup> Indeed, the patent owner is vigorously opposing a rejection of this type in a co-owned case.

### **Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 22, 23, 26, 28, 29, 32 and 33 were rejected as allegedly indefinite. (Office Action, paragraph 7).

The foregoing amendments to these claims obviate these rejections. CIn particular, claims 22 and 23 have been canceled; and claims 29, 32 and 33 do not contain the term “second zinc finger protein-encoding nucleic acid.”. Claim 26 has been amended to depend from claim 1, which recites administration of polynucleotides encoding both the first and second zinc finger proteins, and claim 26 further identifies the promoter that is operably linked to ZFP-encoding sequences. Claim 28 has been amended to clarify that the exogenous agent is not an expression vector.

### **Double Patenting**

Claims 1, 2, 8-12, 14-16, 87, 90, 92-94, 96, 97, 102, 104, and 106 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9, 11, 13, 14, 18-22, 23 and 26 of copending Application No. 09/942,090. (Office Action, paragraph 9). In response, Applicants are unable to determine how the cited claims, directed to a method for identifying a gene, make obvious the pending claims, directed to establishing an association between a known gene and a selected phenotype. Moreover, Applicants are unable to find a disclosure of genes not operably linked to heterologous sequences at paragraph 51 of the cited patent application, as stated in the Office Action. The pending claims are directed to methods of establishing an association between a gene and a phenotype and require selection of at least one gene (steps (i) and (ii) of claim 1 and steps (ii) and (iii) of claim 87). By contrast, claims 1, 9, 11, 13, 14, 18-22, 23 and 26 of copending Application No. 09/942,090 do not require that any gene be provided or selected, but, instead, are directed to methods of identifying a putative gene sequence (*e.g.*, determining whether a sequence is a gene sequence or not). Therefore, the claims of the two applications are not obvious with respect to each other, and, accordingly, Applicants request that this double patenting rejection be withdrawn. In the event that it is maintained, Applicants request that this provisional double patenting rejection be addressed during prosecution of USSN 09/942,090.

Claims 1, 2, 5, 6, 8-33, 87, 88 and 90 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1, 3, 5, 8-10, 12-22, 26, 27,

32, 39-41 and 55 of U.S. Patent No. 6,599,692. (Office Action, paragraph 10).


Applicants submit the appropriate terminal disclaimer herewith.

Claims 1, 9, 10-12, 14-16, 87 and 92 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 4, 9, 11 and 13-22 of copending Application No. 09/941,450. (Office Action, paragraph 11). Applicants first note that this rejection is supported by a citation to page 17 of a different application (USSN 09/942,090 rather than 09/941,450). In any event, pages 17 of both USSN 09/942,090 and 09/941,450 are identical and contain no reference to (1) uses of genes not operably linked to heterologous sequences or (2) negative control of a zinc finger that binds to a second gene. Moreover, the pending claims are directed to methods of establishing an association between a gene and a phenotype and require selection of at least one gene (steps (i) and (ii) of claim 1 and steps (ii) and (iii) of claim 87). By contrast, claims 4, 9, 11 and 13-22 of 09/941,450 do not require that any gene be provided or selected, but, instead, are directed to methods of identifying a putative gene sequence (*e.g.*, determining whether a sequence is a gene sequence or not). Therefore, the claims of the two applications are not obvious with respect to each other, and, accordingly, Applicants request that this double patenting rejection be withdrawn.

**CONCLUSION**

Applicants believe that the claimed subject matter is now in condition for allowance and early notification to that effect is respectfully requested. If any issues remain to be addressed, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

By:   
Dahna S. Pasternak  
Registration No. 41,411

ROBINS & PASTERNAK LLP  
1731 Embarcadero Road  
Suite 230  
Palo Alto, CA 94303  
Telephone: (650) 493-3400  
Facsimile: (650) 493-3440